

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

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| IN RE: ETHICON, INC. PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION | Master File No. 2:12-MD-02327 MDL No. 2327 |
| THIS DOCUMENT RELATES TO WAVE 6 CASES | JOSEPH R. GOODWIN U.S. DISTRICT JUDGE |

**MEMORANDUM IN SUPPORT OF PLAINTIFFS' MOTION TO EXCLUDE OR
OTHERWISE LIMIT THE OPINIONS AND TESTIMONY
OF DEFENSE EXPERT TERENCE J. COLGAN, M.D.**

Plaintiffs respectfully request that this Court exclude or otherwise limit the opinions and testimony proffered by Defendants Ethicon, Inc. and Johnson & Johnson's expert Terence J. Colgan, M.D. ("Dr. Colgan"). In support of their motion, Plaintiffs state as follows:

INTRODUCTION

Dr. Colgan is a board-certified gynecologic pathologist, with a specialty certificate in Anatomical Pathology from both the Royal College of Physicians and Surgeons of Canada and the American Board of Pathology. *See generally* Exhibit C (Expert Report); Exhibit D (Curriculum Vitae). Additionally, Dr. Colgan is the Associate Editor for Anatomical Pathology, *Archives of Pathology and Laboratory Medicine*. Exhibit D, at 4. Plaintiffs do not challenge his qualifications as such. Dr. Colgan is employed at Mount Sinai Hospital ("Sinai Health System") at the University of Toronto in Canada as the Head of the Sections of Gynecological and Cytopathology. Exhibit D, at 1. Specifically, Dr. Colgan works in the Department of Laboratory Medicine and Pathobiology within Sinai Health System. Exhibit D, at 1. Dr. Colgan obtained his medical degree from the University of Toronto, and, after graduation, he completed a "rotating

internship,” which included a surgical and obstetrical and gynecologic rotation, followed by residency training in pathology. Exhibit B (Deposition), 20:1-16; 21:2-8.

Dr. Colgan was approached by Mr. Andrew Snowden, an attorney with Butler Snow LLP, to review medical literature and written reports from Dr. Vladimir Iakovlev, a colleague of Dr. Colgan at the University of Toronto in the Department of Laboratory Medicine and Pathobiology. Exhibit B, 28:16-20. Specifically, Dr. Colgan has been hired to assess, and ultimately call into question, the research conducted by Dr. Iakovlev regarding findings of “possible effects of the placement of mid-urethral mesh slings in the treatment of urinary stress incontinence.” Exhibit C, at 4.

However, as discussed below, Dr. Colgan is unqualified to assess Dr. Iakovlev’s research and published articles because Dr. Colgan lacks expertise in the design, function, and ultimate effects of transvaginal mesh in the human body. Dr. Colgan is not a gynecologist, a uro-oncologist, or a urogynecologist; he does not study degradation or contraction of transvaginal mesh; his primary focus is on the diagnosis of disease through the examination of tissues; he does not seek to identify how the body responds to injury, or more specifically, how the body responds to the placement of transvaginal mesh; and he has never conducted research on vaginal mesh, has never overseen a visiting scholar or fellow conducting research into vaginal mesh or abdominal mesh, and has never presented any papers to a learned society on abdominal or vaginal mesh. Exhibit B, 22:14-23; 23:2-8; 38:1-16; 39:5-9. Therefore, Dr. Colgan’s testimony should be excluded.

LEGAL STANDARD

“A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert’s scientific,

technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.” F.R.E. 702. In the context of Rule 702, “‘knowledge connotes more than subjective belief or unsupported speculation.’” *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 590 (1993). Trial courts must ensure that a purported expert witness “is not merely parroting the opinions of others, but that the matters upon which she will opine are clearly within her area of expertise.” *Bouygues Telecom, S.A. v. Tekelec*, 472 F. Supp. 722, 730 (E.D. N.C. 2007).

If the expert is qualified, “[t]he U.S. Supreme Court [has] established a two-part test to govern the admissibility of [the] expert testimony under Rule 702—the evidence is admitted if it ‘rests on a reliable foundation and is relevant.’” *Tyree v. Boston Scientific Corp.*, 54 F.Supp.3d 501, 516 (S.D. W. Va. 2014) (*quoting Daubert*, 509 U.S. at 597). Although “[t]he proponent of expert testimony does not have the burden to ‘prove’ anything to the court,” he or she must nonetheless “come forward with evidence from which the court can determine that the proffered testimony is properly admissible.” *Id.* (*quoting Md. Cas. Co. v. Therm-O-Disc, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998)).

The Supreme Court has provided a non-exhaustive list of factors for a judge to consider in applying F.R.E. 702: “(1) whether a theory or technique can be or has been tested; (2) whether it has been subjected to peer review and publication; (3) whether a technique has a high known or potential rate of error and whether there are standards controlling its operation; and (4) whether the theory or technique enjoys general acceptance within a relevant scientific community.” *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (*citing Kumho*

Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999); *Daubert*, 509 U.S. at 592-94). “The inquiry to be undertaken by the district court is ‘a flexible one’ focusing on the ‘principles and methodology’ employed by the expert, not on the conclusions reached.” *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (quoting *Daubert*, 509 U.S. at 594-95). Even so, “[e]xpert witnesses have the potential to be both powerful and quite misleading[;]” the [trial] court must ‘ensure that any and all scientific testimony . . . is not only relevant, but reliable.’” *Tyree*, 54 F.Supp.3d at 516 (quoting *Cooper*, 259 F.3d at 199).

ARGUMENT

I. Dr. Colgan’s General Opinions Regarding Dr. Iakovlev’s Research and Published Material Should Be Excluded or Limited.

Dr. Colgan is unqualified to assess the credibility or adequacy of Dr. Iakovlev’s research and published materials because he lacks experience in, and knowledge of, the specific pathology of vaginal mesh to render any meaningful opinions. First, Dr. Colgan lacks proficiency in understanding and studying transvaginal mesh. Additionally, other than his personal opinion, Dr. Colgan offers no foundational support for his contention that Dr. Iakovlev’s pathology research papers do not comport with “good scientific practice.” Exhibit C, at 13. Thus, Dr. Colgan’s testimony should be excluded.

A. Dr. Colgan is Unqualified to Assess the Credibility or Adequacy of Dr. Iakovlev’s Research and Published Materials Because He Lacks Experience In, and Knowledge of, The Specific Pathology of Vaginal Mesh.

To begin, Dr. Colgan lacks the necessary expertise to offer general opinions on the credibility and adequacy of any research paper authored by an actual expert, like Dr. Iakovlev, in the pathology of transvaginal mesh. Dr. Iakovlev has published numerous articles regarding the study of transvaginal mesh, and he has also participated in multiple lectures, workshops, and visiting professorships regarding the pathology associated with mesh. Surprisingly, although

they both work for the same institution, Dr. Colgan has never attended any of these events and does not know Dr. Iakovlev personally. Exhibit B, 39:10-17; 55:9-12. Further, Dr. Colgan explicitly states that he does not hold himself out to be an expert in vaginal mesh or in the pathology associated with mesh utilized for herniorrhaphy or abdominal repairs:

20 Q. And at that time, did you hold
21 yourself out to be an expert in pathology
22 associated with vaginal mesh?

23 A. I did not hold myself out to be an
24 expert in vaginal mesh.

Exhibit B, 41:20-24.

4 Q. Okay. Do you have any expertise
5 in the pathology associated with mesh utilized for
6 herniorrhaphy or abdominal repairs?

7 A. No, I do not.

Exhibit B, 42:4-7.

Moreover, not only did Dr. Colgan state that he sees over 5,000 cases “per annum,” where only less than one percent of them actually involve mesh, *see* Exhibit B, 46:13-25; 47: 9-12, he was also unable to estimate the number of transvaginal mesh devices that are submitted to his Department at the University of Toronto. Exhibit B, 47:24-25; 48:1-3. This lack of knowledge highlights the uncertainty in Dr. Colgan’s understanding of transvaginal mesh. A reliable expert opinion must be based on scientific, technical, or other specialized knowledge and not on belief or speculation, and inferences must be derived using scientific or other valid methods.” *Oglesby v. General Motors Corp.*, 190 F.3d 244, 250 (4th Cir.1999). Therefore, Dr. Colgan cannot give general or specific opinions on how transvaginal mesh affects and interacts, contemporaneously, with the human body because he lacks any specialized education, training, or applicable relevant experience specifically related to the study of the pathology of

transvaginal mesh. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 260 (4th Cir. 1999) (noting that the reasoning or methodology used by an expert witness as foundational support for his opinions must be “supported by adequate validation to render it trustworthy”). Dr. Colgan plainly fails to meet this standard because he has offered no validation, other than his personal opinion, to support his contention that Dr. Iakovlev’s reports lacks merit.

Moving forward, subsequent to Dr. Colgan reviewing Dr. Iakovlev’s pertinent research papers, which Dr. Colgan discovered only after Mr. Snowden brought them to his attention, Dr. Colgan did not address any of his alleged “concerns” regarding the research papers with any authoritative body at the University of Toronto or the publishing journal, the Journal of Biomedical Materials Research Part B: Applied Biomaterials. Exhibit B, 67:23-25; 68:4-11; 69:5-20. Additionally, Dr. Colgan is unaware of the number of research articles that have cited Dr. Iakovlev’s work, thus lacking any knowledge of whether his “concerns” embody the general consensus of Dr. Iakovlev’s research papers in the field of pathology in transvaginal mesh. Exhibit B, 71:15-19. Moreover, Dr. Colgan has not read any of Dr. Iakovlev’s other research articles discussing transvaginal mesh, thus raising skepticism over whether Dr. Colgan has read enough articles, or any at all, to warrant his opinions on whether Dr. Iakovlev’s hypothesis on transvaginal mesh is grounded and accurate. Exhibit B, 127:15-17.

Dr. Colgan also fails to give any mention to, or discussion of, opposing viewpoints on this matter; he does not give any credence to the countless articles and research papers that parallel Dr. Iakovlev’s hypothesis that transvaginal mesh has a high potential for side effects, such as degradation and contraction:¹

¹ See Feiner, B & Maher, C., *Vaginal Mesh Contraction: Definition, Clinical Presentation, and Management*, Obstet & Gynecol (2010) 115(2):325-339 (“Vaginal mesh contraction is a serious complication after prolapse repair with armed polypropylene mesh that is associated with substantial morbidity, frequently requiring surgical intervention. Research and development is urgently needed for newer graft materials with diminished shrinkage properties.”).

1Q. And in your search for writing
2 your expert opinion where, in your opinion, there's
3 little to no evidence that mesh contracts, you did
4 not find the paper "Vaginal mesh contraction"; do
5 you agree?

6 A. I must not have.

Exhibit B, 156:1-6.

As this Court has observed, “[a]n expert’s opinion may be unreliable if he fails to account for contrary scientific literature and instead ‘selectively [chooses] his support from the scientific landscape.’” *Tyree*, 54 F. Supp. 3d at 520 (S.D.W. Va. 2014) (quoting *In re Rezulin Products Liab. Litig.*, 369 F.Supp.2d 398, 425 (S.D.N.Y. 2005) (quotations omitted)). Where, as here, the “relevant scientific literature contains evidence tending to refute the expert’s theory and the expert does not acknowledge or account for that evidence, the expert’s opinion is unreliable.” *Id.*

Consequently, Dr. Colgan’s opinions and testimony regarding Dr. Iakovlev’s research papers and published articles should be excluded because he lacks sufficient knowledge and experience with transvaginal mesh to render such opinions and give any meaningful comment.

B. Dr. Colgan Offers No Foundational Support for His Contention that Dr. Iakovlev’s Pathology Research Papers Do Not Comport With “Good Scientific Practice.”

Dr. Colgan proffers baseless assertions regarding the credibility of Dr. Iakovlev’s research papers, and gives no underlying support for his reasoning as to why Dr. Iakovlev’s papers fail to meet certain standards. First, Dr. Colgan attempts to attack Dr. Iakovlev’s research papers by focusing on the structure of the paper and the words used within the paper, rather than focusing on the actual substance. In support of this, Dr. Colgan erroneously relies on “standard of care” position papers, written by Obstetricians and Gynecologists in Australia and New Zealand, to discredit Dr. Iakovlev’s conclusions regarding mesh degradation. Exhibit B, 121:21-

25; Exhibit C, at 15. Additionally, to attack Dr. Iakovlev's work, Dr. Colgan "cherry-picks" certain parts of it in an attempt to distract from the overall conclusion of the research, which is that transvaginal mesh can pose serious complications to individuals. This practice lacks any sound foundation and cannot be acknowledged. Therefore, Dr. Colgan should be precluded from offering any testimony or opinion regarding any aspect of Dr. Iakovlev's research papers.

To begin, Dr. Colgan heavily emphasizes his disapproval of Dr. Iakovlev's choice of placement of certain findings throughout the research paper:

16 That scientific method has been
17 fulfilled in this paper. It's just your criticism
18 of where they put the language; correct?

19 MR. DAVIS: Object to the form.

20 THE WITNESS: They did attempt to write
21 a scientific paper.

22 BY MR. RESTAINO:
23 Q. And it was published in the
24 peer-reviewed medical literature?
25 A. It was published in a
1 peer-reviewed journal.

Exhibit B, 102:16-25; 103:1.

Dr. Colgan's concern over the placement of terms throughout the paper is unnecessary and distracting. Dr. Colgan even attacks Dr. Iakovlev's paper as not adhering "to good scientific practice" because of such placement, notwithstanding the fact that it was peer-reviewed and published in a peer-reviewed medical journal. Exhibit C, at 13. Merely because Dr. Colgan has personal distaste in peer-reviewed material, notwithstanding the fact that he conducts peer-reviews for Gynecologic Oncology, does not render such practice invalid or without authority. Exhibit B, 45:21-23. Further, in support of Dr. Colgan's contention that Dr. Iakovlev's papers fail to conform to good scientific practice, he cites to the Royal Australian and New Zealand

College of Obstetricians and Gynecologists standard of care position paper that recommends the use of polypropylene tapes in sling surgeries for stress urinary incontinence. Exhibit C, at 15. However, this paper has nothing to do with mesh degradation or mesh pathology, and there is no evidence that this paper represents the general opinion of medical doctors in the United States:

3 Q. And you describe this as an
4 authoritative and independent body; correct?

5 A. Correct.

Exhibit B, 123:2-4

17 Q. In your expert opinion, what is it
18 about this organization that makes it
19 "authoritative"?

20 A. I believe that the Australian and
21 New Zealanders are well-respected with to their
22 practice of medicine.

23 Q. Do you have any objective basis
24 for that statement?

25 A. Only 25 years' experience.

1 Q. That would be anecdotal. Would
2 you agree?

3 A. Yes.

Exhibit B, 124:17-25; 125:1-3.

This “anecdotal” statement is not sound reasoning or support for Dr. Colgan’s assertion that Dr. Iakovlev’s research papers lack “good scientific practice.” *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) (stating that “nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the *ipse dixit* of the expert”). Therefore, Dr. Colgan’s assertions that Dr. Iakovlev failed to meet scientific standards is baseless and should be precluded.

Next, Dr. Colgan employs a “pick and choose” method, with regards to Dr. Iakovlev’s research paper, to focus only on certain parts of the research paper he finds questionable. This practice is unreliable and ungrounded. *See E.E.O.C. v. Freeman*, 778 F.3d 463, 469 (4th Cir. 2015) (noting that courts routinely exclude expert testimony that ‘cherry-picks’ data). For example, Dr. Colgan states that he did not comment on every part of Dr. Iakovlev’s expert report, but that his opinions still stand as correct:

10 You didn't put in the report to the
 11 judge Component 8. And in Component 8, he actually
 12 writes about innervation of the female genital
 13 organs:

14 "Furthermore, the female
 15 genital area has much higher nerve
 16 density compared to the midline
 17 anterior abdominal wall and the
 18 groin. The scar inhabiting and
 19 surrounding the transvaginal meshes
 20 has the highest nerve density out of
 21 all explanted surgical meshes I have
 22 examined as a pathologist. Thus
 23 placement of the vaginal mesh is
 24 associated with higher risk for
 25 chronic pain than the placement of
 1 the mesh for hernia repair, either
 2 ventral or in the groin."

3 [As read.]

4 Did I read that correctly?

5 A. I accept that you did.

6 Q. And you did not include that in
 7 your expert report?

8 A. I did not comment on every
 9 component; this is correct, but it still does not
 10 change my opinion on what I wrote under Component
 11 9, that what he said about stiff, irregular
 12 mesh-scar plate under sensitive mucosa is
 13 speculation by a histopathologist based upon
 14 histopathology alone.

Exhibit B, 141:10-25; 142:1-14.

Once again, Dr. Colgan is not an expert in the pathology of transvaginal mesh, nor is he an expert in the use of midurethral slings for treatment of urinary stress incontinence. Dr. Colgan even concedes that he is quite unfamiliar with the medical literature given to him by Mr. Snowden in his General Reliance List, even though in his Expert Report he cited to material within the list to support his contentions:

2 Q. The document is titled a "General
3 Reliance List".
4 Is it your testimony that you have not
5 reviewed and are not relying upon every article
6 that's in there? Because I won't go through many
7 of them if that's the case.

8 MR. DAVIS: Object to the form.

9 THE WITNESS: I have not relied on
10 every article in this extensive list.

11 BY MR. RESTAINO:
12 Q. Did you make this list up or did
13 someone make it up for you?

14 A. As I mentioned previously, I have
15 not seen this list.

Exhibit B, 18:2-15.

The pertinent question to the analysis of Dr. Colgan's viewpoint is not whether Dr. Colgan is right or wrong; Plaintiffs do not need to challenge these opinions based on their accuracy. *See Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir.1999) (the focus is on the principles and methodology, not the conclusions reached. Further, the court need not determine if expert testimony is irrefutable or necessarily correct). The question rests on whether Dr. Colgan properly formulated his opinions in a way that comports with scientific standards. Clearly, he did not.

For example, in his expert report, Dr. Colgan relies on an article by Hill et al., titled Histopathology of Excised Midurethral Sling Mesh,² which aims to “compare the histological characteristics of pathological specimens of excised midurethral sling mesh and surrounding vaginal tissue in patients who presented preoperatively with pain and/or exposure of mesh to patients who underwent mesh excision for voiding dysfunction without pain and/or erosion.”³ The Hill article, like Dr. Iakovlev’s article, is an observational, “retrospective case-control study.” Exhibit B, 88:19-25; 89:1-8. However, although Dr. Colgan praises the Hill article, which utilizes the same methodology as Dr. Iakovlev’s study, he criticizes Dr. Iakovlev’s article for its alleged deficiencies in controlling or eliminating the “potential confounding variables” present with observational, retrospective case-controlled studies. Exhibit C, at 13. This contradiction warrants skepticism; both studies adhere to the same approach and methodology. Dr. Colgan cannot attack Dr. Iakovlev’s article while praising another article with the same potential “deficiencies.” Moreover, while Dr. Colgan heavily focuses on the use of clinical data in the Hill article, he failed to acknowledge the limitations and potential bias within this article:

7 Q. The authors of the Hill paper did
8 not have access to all of the index surgical
9 operative reports; therefore, they had to rely upon
10 subject recall, as documented in the electronic
11 medical record, for some of the data.

12 And that is a weakness and source of
13 bias in a retrospective case-control study, is it
14 not?

15 MR. DAVIS: Object to the form.

16 THE WITNESS: The... There are often
17 limitations in the amount of clinical data one can
18 obtain, either through a practical availability or
19 ethic board approval, but this doesn't change the

² Hill et al., *Histopathology of excised midurethral sling mesh*, Int Urogynecol J (2015) 26: 591-95. <https://doi.org/10.1007/s00192-014-2553-0>

³ *Id.*

20 fact that they did get some clinical data which is
21 not present in Iakovlev's paper.

22 BY MR. RESTAINO:

23 Q. In fact, they were able to obtain
24 only 55 percent of the index surgical operative
25 reports, and without the index operative surgical
1 report, the authors are -- the authors were unable,
2 in 45 percent of the cases, to analyze potential
3 risk factors that may have led to increased levels
4 of inflammation, including the date of the index
5 mesh placement, because there's acute inflammation
6 associated with surgery; correct?

7 MR. DAVIS: Object to the form.

8 THE WITNESS: Acute inflammation is
9 usually seen upon initial insertion of the mesh,
10 yes.

11 BY MR. RESTAINO:

12 Q. And the type of mesh utilized;
13 there are different inflammatory responses
14 dependent upon the type of mesh utilized.
15 Would you agree?

16 A. I'm not an expert in the
17 examination of -- of mesh.

Exhibit B, 91:7-25; 92:1-17.

This lack of knowledge and sound reasoning highlights the ultimate deficiencies in Dr. Colgan's testimony.

Finally, Dr. Colgan attempts to manipulate Dr. Iakovlev's findings to negate his hypothesis:

3 Q. On page 14, right above the
4 section "Response to Dr. Iakovlev's Expert Report",
5 that one-sentence paragraph, you write:
6 "In this paper Dr. Iakovlev
7 concludes that the mechanism leading
8 to mesh-related complications is
9 unclear, through his statement,

10 '...the exact mechanisms of these
11 late complications are yet to be
12 understood,'."
13 Did I read that correctly?

14 A. Yes, you did.

15 Q. Now, in fact, if you turn to page
16 10 of Dr. Iakovlev's paper, there's a section on
17 the left column... Are you there, sir?
18 A. Yes.

19 Q. Okay. ...that says "Clinical
20 significance of polypropylene degradation".
21 Do you see that?

22 A. Yes.

23 Q. And in the second paragraph where
24 I believe you're attempting to quote from, he
25 writes:

1 "The clinical descriptions
2 provided with the specimens
3 indicated that in many cases,
4 mesh-related complications develop
5 several years after mesh
6 implantation. The exact mechanisms
7 of these late complications are yet
8 to be understood, however factors
9 accumulating over time need to be
10 considered as primary contributors."
11 Did I read that correctly?

12 A. Yes, you did.

13 Q. That's not what you quoted in your
14 paper.

15 A. I quoted –

16 MR. DAVIS: Object to form.

17 THE WITNESS: I quoted partially. I
18 didn't put in the entire sentence.

Exhibit B, 110:3-25; 111:1-18.

This “misinterpretation” renders Dr. Colgan’s testimony unreliable and inadmissible because it rests on inaccurate and misleading information. Dr. Colgan did not use a reliable methodology in forming his opinions in his expert report on the credibility of Dr. Iakovlev’s research papers. Dr. Colgan failed to give a convincing story that he relied on more than his own belief. “Courts widely agree that ‘trial judges may evaluate the data offered to support an expert's bottom-line opinions to determine if that data provides adequate support to mark the expert's testimony as reliable.’” *E.E.O.C.*, 778 F.3d at 472 (quoting *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997)). It is evident here that Dr. Colgan’s evidentiary and supporting data does not reach the standard level of reliability necessary to render this testimony valid.

On these grounds, Dr. Colgan’s opinions and testimony should be excluded because they lack any and all foundation in sound reasoning and understanding.

CONCLUSION

Due to the foregoing, Plaintiffs respectfully request that this Court grant their motion and exclude or otherwise limit the opinions and testimony of Dr. Colgan. Plaintiffs further request all other relief to which they are entitled.

Respectfully submitted,

/s/ D. RENEE BAGGETT

Bryan F. Aylstock, Esq.

Renee Baggett, Esq.

Aylstock, Witkin, Kreis and Overholtz, PLC

17 East Main Street, Suite 200

Pensacola, Florida 32563

(850) 202-1010

(850) 916-7449 (fax)

baylstock@awkolaw.com

rbaggett@awkolaw.com

Attorneys for Plaintiffs

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